CV19-5125

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GARAUFIS, J.

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, AND THE CITY OF NEW YORK *ex rel.* OMNI HEALTHCARE INC.

Plaintiffs,

v.

U.S. ONCOLOGY, INC.

Defendant

BLOOM, M.J.

FILED *IN CAMERA* AND UNDER SEAL

DO NOT ENTER INTO PACER

JURY TRIAL DEMANDED

FALSE CLAIMS ACT COMPLAINT

On behalf of the United States of America, the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington and Wisconsin, the District of Columbia, and the cities of Chicago and New York, Plaintiff and Relator Omni Healthcare Inc. ("Relator" or "Omni") files this *qui tam* complaint against Defendant U.S. Oncology, Inc. and U.S. Oncology Network

("Defendant") under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), and the False Claims Acts of the District of Columbia, states, and cities described herein:

INTRODUCTION

1. U.S. Oncology Inc. operates more than 450 cancer treatment center locations nationwide, with more than 1,400 affiliated physicians treating more than 995,000 patients annually in a network called the U.S. Oncology Network ("the Network"). Beginning in 2005, U.S. Oncology Inc. also distributed pharmaceutical drugs to the Network through U.S. Oncology Specialty LP. At all relevant times, U.S. Oncology dominated and controlled U.S. Oncology Specialty, LP, the U.S. Oncology Network, and the subsidiaries and affiliates operating within it with respect to Overfill Harvesting and related claim-submission policies, and made all material determinations relating to same. Defendant U.S. Oncology Inc. will be referred to as "Defendant" or "U.S. Oncology."

2. This action describes unlawful business practices used by Defendant that knowingly and intentionally put cancer patients and others with compromised immune systems at serious risk for infection, and defrauded the federal, state and local governments out of hundreds of millions of dollars.

3. This action arises from Defendant's unlawful conduct in connection with its harvesting of overfill from certain cancer drugs and administering the overfill to cancer patients and other immuno-compromised patients (the "Overfill Harvesting"). The drugs at issue include but are not limited to: Aranesp, Aloxi®, Procrit®, Neupogen, Anzemet, Kytril (both brand and generic) and Taxotere, and all other cancer drugs which come already packaged by the original manufacturer in single dose and/or multi-dose vials (the "Oncology Drugs").

Abraxane
Alimata
Aloxi
Anzemet
Aranesp
Avastin
Eloxatin
Erbitux
Gemzar, gemcitabine hydrochloride
Herceptin
Keytruda
Kytril
Neulasta, pegfilgrastim
Neupogen, filgrastim
Opdivo
Procrit
Reclast, zoledronic acid
Remicade
Rituxan
Taxol
Taxotere
Velcade
Zometa, zoledronic acid
Zytiga

4. To ensure that a doctor is able to withdraw the full amount of a drug sold in an FDA-approved container, typically a glass vial, these Oncology Drugs contain more than the amount indicated on the label. This excess amount is called "overfill." Providers are not allowed to bill for any excess drug such as overfill for which the drug manufacturer does not charge.

5. Moreover, these vials are expressly marked for "single use," i.e., contents may be extracted only once because they do not contain preservatives or antiseptic chemicals to prevent bacterial or fungal growth.

6. Nevertheless, U.S. Oncology and its physicians learned that it could maximize profits at the government's and private insurer's expense by harvesting this overfill and pooling Oncology Drugs in order to seek reimbursement for drugs U.S. Oncology received at no cost from the manufacturer.

7. Defendant's Overfill Harvesting violated virtually all requirements that the government has put in place to meet in manufacturing, processing, labeling, packing, and holding drugs to ensure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess.

8. The harvesting of the Oncology Drugs also makes it difficult to trace the precise origins of the drug administered to patients back to its correct manufacturer batch and lot (a drug's "Pedigree") – something that is necessary for health officials in the event of contamination or other issues with the medication. Defendant focused its Overfill Harvesting on Oncology Drugs administered to patients already prone to infection to increase its chances of its unlawful conduct going undetected. Defendant, of course, knew that any infections and resulting patient deaths would likely be falsely attributed to the patients' disease and treatment, as opposed to healthcare providers' unwittingly administering non-sterile and unapproved drugs.

9. But the effects of Defendant's Overfill Harvesting extend beyond fraudulent reimbursements Defendant received for the no-cost drug overfill. The program artificially inflated the Average Sales Price ("ASP") used by the government to determine reimbursement rates for the Oncology Drugs – including those used for all reimbursements for lawful sales of the drugs in their original manufacturer packaging.

10. As outlined below, Defendant caused false claims for reimbursement to be submitted to and honored by the United States, numerous states and cities – claims that would not

have been paid had these governments known of Defendant's improper and unsafe practices. Physicians and other providers at U.S. Oncology locations around the country participated in the Overfill Harvesting and submitted false and fraudulent claims for payment for the drugs administered from the no-cost overfill.

11. The false or fraudulent claims and statements at issue involve payments for prescription drugs made by: (i) Federal Government-funded health assistance programs, including Medicaid and Medicare; and (ii) direct Federal Government purchases, including payments made by the United States Department of Defense ("DOD") and the United States Department of Veterans Affairs ("VA"). The false or fraudulent claims and statements at issue also involve payments made by state or local government-funded health assistance programs, including Medicaid, and payments made by other state or local government-funded agencies or entities.

12. The false and fraudulent claims and statements were also made to private insurers in all states, but in particular to private insurers in California and Illinois, which have enacted anti-fraud statutes encouraging whistleblowers to bring lawsuits against those who perpetrate frauds on private insurance companies, which fraud raises premiums for the insured and increases the costs of private insurers.

13. Defendant's conduct also artificially inflated the Average Sales Price used by the government to calculate the reimbursement amount for all of the Oncology Drugs, thus causing the federal, state and local governments to overpay for every reimbursement on these drugs – even those solely in the original manufacturer's packaging.

14. At all times, Defendant knew that its conduct was illegal or, at the very least, Defendant acted in reckless disregard of the law and patient safety, for the sole purpose of increasing profitability and market share.

15. This is an action to recover treble damages and civil penalties on behalf of the United States of America, the District of Columbia, states, and cities in connection with Defendant's violations of the FCA and the False Claims Acts of the District of Columbia and the specified states and cities, as well as under common law theories of payment by mistake and unjust enrichment. Like its equivalent local statutes, the FCA provides, *inter alia*, that any person who knowingly presents and/or causes to be presented to the United States a false or fraudulent claim for payment is liable for a civil penalty of up to $21,000 for each claim submitted, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729. The FCA also allows any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. 31 U.S.C. § 3730.

16. This is also an action under the Illinois Insurance Claims Fraud Prevention Act, ("IICFP") 740 ILCS 92/5, and the California Insurance Claims Fraud Prevention Act, ("CIFPA"), Section 1871.7 of the California Insurance Code. Under these statutes whistleblowers are encouraged to file suit on behalf of California and Illinois against those engaged in fraud against private insurers.

17. The interest of Illinois and California in defeating private insurance fraud is substantial in that fraudulent claims to private insurance companies can impose extraordinary costs on insurers and insureds through wrongful conduct that is largely hidden from plain view.

JURISDICTION AND VENUE

18. This Court has jurisdiction pursuant to 31 U.S.C. § 3732, and concurrent jurisdiction over state law claims because those claims arise from the same transaction or occurrence giving rise to the claims brought under the FCA.

19. Additionally, pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular the FCA. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the remaining claims on the grounds that those claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

20. At all relevant times, Defendant regularly conducted substantial business within the State of New York, maintained permanent employees in the State of New York, and made, and are making, significant sales and claims for reimbursement in the State of New York, within this judicial district.

21. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), which provides that any action brought under § 3730 may be brought in any judicial district in which the defendant or, in the case of multiple Defendant, any one defendant, can be found, resides, transacts business, or in which any act proscribed by § 3729 occurred. The acts complained of herein occurred in the state of New York within this judicial district, as well as nationwide. Additionally, venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1)-(2).

FILING UNDER SEAL

22. Under the FCA, as well as the False Claims Acts of the District of Columbia, states and cities, pleadings are to be filed *in camera* and remain under seal for a period of at least sixty (60) days, and shall not be served on Defendant until the Court so orders.

23. As required by 31 U.S.C. § 3730(b)(2), Relator voluntarily submitted prior to the filing of this Complaint a confidential written disclosure statement (subject to the attorney-client privilege) to the United States Government, containing materials, evidence, and information in its

possession pertaining to the allegations contained in this Complaint. Relator also voluntarily submitted a confidential written disclosure statement and this Complaint to the District of Columbia, as well as the states and cities under whose FCAs this action is partially brought.

PARTIES

24. Relator, Omni Healthcare, Inc., is a professional medical company primarily based in Brevard County, Florida. It serves patients in the practice of hematology/oncology throughout central Florida. It practices through physicians in central Florida, and specializes in the field of internal medicine with a subspecialty in hematology and oncology. Relator, through its principals, regularly treats cancer patients on both an inpatient and outpatient basis and regularly purchases drugs from various distributors and wholesalers to treat its patients for both the underlying disease condition, as well as for the other conditions associated with cancer and attendant side effects.

25. Relator is an original source of the facts and information hereinafter set forth concerning the activities of the Defendant relative to the Overfill Harvesting and the adulterated, no-cost overfill that is being improperly billed to Medicare, the states' Medicaid Programs, and other federal, private, state and city reimbursement programs. The facts averred herein are based upon the personal knowledge Relator's principal, and documents and information in his possession, which were acquired by him in connection with his work as an oncologist treating patients with cancer.

26. Defendant U.S. Oncology, Inc. ("U.S. Oncology"), is a Delaware corporation with a principal place of business in The Woodlands, Texas. U.S. Oncology was purchased by McKesson in December 2010 and is now a wholly owned subsidiary of Defendant McKesson and operating in a division known as "McKesson Specialty Health."

27. Defendant U.S. Oncology Network is a trade name used by U.S. Oncology Inc. to identify its network of physicians and oncology centers.

28. Relevant to this action, according to US Oncology, it "helps expand and improve patient access to high quality, integrated and advanced cancer care by working closely with physicians, pharmaceutical manufacturers and payers to improve the safety, efficiency and effectiveness of the cancer care delivery system" and "provides drug distribution and specialty pharmacy services" that "aim to increase patient access to pharmaceuticals through a safe and efficient delivery system." [10-K for year ending December 21, 2009]. US Oncology and its subsidiaries "provide extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced cancer care treatments, build integrated community-based cancer care centers, improve their therapeutic drug management programs, and participate in cancer-related clinical research studies. US Oncology also provides a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting and analysis." According to U.S. Oncology: "Because of the significant size and scale of our network, we negotiate all pharmaceutical purchases directly with drug manufacturers and are generally able to procure market-differentiated pricing. In addition, we work with affiliated practices to implement efficient operating processes to manage inventory, eliminate waste and enhance product safety."

29. According to U.S. Oncology: "The majority of pharmaceuticals we purchase are delivered to the affiliated practices where they are mixed, when required, by pharmacists, pharmacy technicians or nurses employed by the affiliated practices and administered to patients at the practice. A small percentage of pharmaceuticals we purchase are dispensed to patients at our network pharmacies to be used on an outpatient basis. As of December 31, 2009, our network

includes 46 licensed pharmacies (located primarily in our cancer centers), 142 pharmacists and 360 pharmacy technicians. Where appropriate, we establish, or assist practices in establishing, retail pharmacy locations for oral and other self-administered therapies. The pharmacies serve as the recipients of, and distributors for, the pharmaceuticals used in treating our affiliated practices' patients." 10-K December 31, 2009.

30. U.S. Oncology also claimed to provide "a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting and analysis."

31. In 2005, U.S. Oncology launched U.S. Oncology Specialty, LP, "a specialty pharmaceutical distribution business to facilitate the flow of oncology pharmaceuticals from the pharmaceutical manufacturers to their network of over 1,400 oncologists nationwide." From at least 2005 through and after the time of its acquisition by McKesson, U.S. Oncology provided oncologists with pharmaceutical distribution services described as:

> Our distribution center increases the safety of drugs through a state-of-the-art e-Pedigree technology that tracks drug therapies from the manufacturer to the practice, ensuring that drugs administered to patients by our affiliated physicians are genuine and unadulterated. Located in Fort Worth, Texas, our distribution center supplied approximately 95% of the value of pharmaceuticals administered by our network of affiliated practices in 2009. [10K December 31, 2009]

32. At the time of its acquisition by McKesson, US Oncology distributed 2.4 billion dollars-worth of oncology pharmaceuticals annually and operated eighty three comprehensive cancer centers. It was affiliated with 1,400 physicians operating in over 400 locations, including 99 radiation oncology facilities in 39 states that treated over 900,000 patients annually. In addition, Governmental programs, such as Medicare and Medicaid, were collectively the affiliated practices' largest payers. At the time of its acquisition by McKesson, U.S. Oncology represented

approximately sixteen percent of the oncology market in the United States [10K December 31, 2009].

33. "For the three months ended September 30, 2010 and 2009, the affiliated practices under comprehensive service agreements derived 41.2% and 39.6%, respectively, of their net patient revenue from services provided under the Medicare program (of which 7.6% and 7.2%, respectively, relate to Medicare managed care) and 4.2% and 3.8%, respectively, from services provided under state Medicaid programs." [Q3 2010 10Q].

A. The False Claims Act.

34. The FCA, 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $16,000 and $21,000 per claim for claims made on or after September 29, 1999.

35. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $16,000 and $21,000 per claim for claims made on or after September 29, 1999.

36. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person, who conspires to commit a violation of the FCA, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $16,000 and $21,000 per claim for claims made on or after September 29, 1999.

37. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

38. The FCA, 31 U.S.C. § 3729(b)(1) provides that "(1) the terms 'knowing' and 'knowingly' -- (A) mean that a person, with respect to information -- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

39. The FCA, 31 U.S.C. § 3729(b)(4) provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

B. The California and Illinois Private Insurance Claims Acts.

40. Under the California Private Insurance Claims Act it is a violation to knowingly make or cause to be made a false or fraudulent material statement or representation for the purpose of obtaining any compensation, or to knowingly assist, abet, conspire with, or solicit a person in an unlawful act under the California Private Insurers Claims Act. Cal. Ins. Code § 1871.4.

41. Under the Illinois Insurance Claims Fraud Prevention Act, it is a violation to knowingly offer to pay or to pay an remuneration directly or indirectly, in cash or in kind, to induce any person to procure patients to obtain services or benefits under a contract of insurance that will be the basis for a claim against an insured person or the person's insurer. Illinois Code, 740 ILCS 92/1.

C. The Anti-Kickback Statute.

40. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population.

41. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

42. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of

their medical assistance programs." H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.

43. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

44. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay, paying or soliciting any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

45. The statute provides, in pertinent part:

> (b) Illegal remunerations
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
>
> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
>
> (B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both. 42 U.S.C. § 1320a-7b(b).

46. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services the ("HHS OIG") to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback

Statute. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994).

47. The Anti-Kickback Statute not only prohibits either the offer or acceptance of outright bribes and rebate schemes, but also prohibits any payment or other remuneration by a drug company to a physician or other person which has as one of its purposes the inducement of the physician to write prescriptions for the company's pharmaceutical products or the inducement of the physician to influence or recommend the prescribing of the product.

48. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid reimbursement is sought.

49. Under 42 U.S.C. § 1395y(a)(1)(A), "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury. . . ."

50. The Second Circuit has held that, "[s]ince § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, Defendant's submission of the claim forms implicitly certifies compliance with its provision." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001).

51. Kickbacks are, by definition, not "reasonable and necessary for the diagnosis or treatment of illness or injury."

52. Federal law makes clear that violation of the Anti-Kickback Statute can support false claims liability.

D. The Government-Funded Programs

53. The Center for Medicare & Medicaid Services ("CMS") is a federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer the Medicaid program.

54. Medicaid is the nation's medical assistance program for the needy, the medically-needy aged, blind and disabled in families with dependent children. *See* 42 USC §§ 1396-1396v. Medicaid is largely administered by the states and funded by a combination of federal and state funds. Approximately fifty-seven percent of Medicaid funding is provided by the Federal Government on a national basis. Among other forms of medical assistance, the Medicaid programs cover outpatient prescription drugs. 42 U.S.C. §§ 1397a(10)(A), 1396d(a)(12).

55. Medicare is the nation's health program for persons over sixty-five years of age and persons who are disabled. Medicare is funded by the Federal Government. Medicare Part B has long covered outpatient prescription drugs that are provided to a patient "incident to" a physician's services, including injectable medications, and drugs that are required for the effective use of durable medical equipment. 42 USC § 1395x(s)(2)(A). Commencing on January 1, 2006, Medicare Part D provided comprehensive outpatient prescription drug coverage for brand name and generic drugs according to National and Local Coverage Determinations. Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173.

56. The VA provides medical assistance, including prescription drug coverage, to persons who have been discharged from active duty service in the military, naval, or air services.

57. The United States Public Health Service ("PHS") provides funding, including outpatient drug coverage, for entities such as black lung clinics, AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, disproportionate

share hospitals, and other entities listed in § 340B(a)(4) of the Public Health Service Act, 42 U.S.C. § 201 et seq.

58. The DOD administers the TRICARE health care program for active duty and retired members of the uniformed services, their families, and survivors. TRICARE benefits include comprehensive prescription drug coverage.

59. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, et seq.; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. See id.

60. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of health care services in the United States. That agreement represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

61. In other words, if a provider tells CMS or its agent that it provided goods or services in violation of the Anti-Kickback Statute, that were not medically unnecessary, that were performed solely for the profit of the provider, and/or that violated another relevant law, CMS will not pay the claim.

62. CMS will also not pay a claim relating to reimbursement for goods or services that were not actually provided.

I. GENERAL ALLEGATIONS

A. General Description of Pharmaceutical Industry.

63. In the broadest terms, in the United States, prescription drugs (pharmaceuticals) and biologics are manufactured by drug manufacturers. Most drug manufacturers manufacture either brand name drugs or generic drugs, but some manufacture both. The manufacturer places the drug into the legally-approved container, labels the drugs with all the information and data required by the governing laws and regulations, labels the drugs with pedigree information such as lot numbers so that anyone receiving the drug down chain can identify its exact date and location of manufacture, and packages the drugs for distribution in government-approved packaging.

64. Wholesale distributors then purchase the drugs from the manufacturers and provide the operational infrastructure necessary to distribute the drugs further such as warehouse facilities, distribution vehicles, and inventory control systems.

65. Wholesale distributors generally deliver the drug products to pharmacies who, in turn, distribute the drugs to physicians or directly to the consumers. Wholesale distributors can also distribute drug products directly to oncology centers, medical practices, and physicians (collectively, "healthcare providers"). Certain pharmacies purchase drug products directly from the manufacturer. There are also specialty pharmacies that specialize in the distribution of more expensive, complex drug products such as self-injectable drugs and biologics.

66. The healthcare providers would then administer the Oncology Drugs to the patients and seek reimbursement from the federal, state and city healthcare programs described below.

B. Injectable Vials and Overfill.

67. Non-sterile, contaminated, or incorrectly dosed drug products are especially dangerous when administered into vascular systems.

68. Thus, injectable drugs are often manufactured, packaged, and sold in single-use (dose) and multi-use (dose) sterile, glass vials.

69. Many drugs for cancer patients and for patients who are suffering from anemia, or nausea and vomiting, are manufactured in single-dose vials, meaning one vial per use per patient. Some drugs are manufactured in pre-filled single-dose syringes. And some are manufactured in multi-dose vials, meaning multiple injections for the same patient over a period of time, or multiple injections for multiple patients out of the same vial.

70. As with other FDA-approved drugs, each of these drugs has its own unique drug codes, or NDCs, which vary for each individual drug based on distribution method (vial, syringe, or auto-injector) and by the dose and quantity of the drug.

71. The amount of drug contained in each vial and the packaging of such drug for injection are pre-approved by the FDA and part of the package label.

72. Because there can be a slight loss of drug product from the withdrawal of the product from the original manufacturer container, the United States Pharmacopeia ("USP") requires that injectable drug vials contain a volume overage in "slight excess" of the labeled volume fill amount to permit withdrawal and administration of the label fill volume amounts. USP Reference Standards, XXXI Rockfield, MD: (2008 Chapter 1151, page 619). This "slight excess" fill volume, or overage, is commonly referred to as the "overfill."

73. The sole purpose of overfill in a vial is to enable a medical provider to extract and administer the full labeled dose as prescribed by the physician and as approved by the FDA.

74. For as long as the Oncology Drugs have been on the market, the USP has recommended up to an additional 1 milliliter, or ten percent overfill for a filled volume of up to one milliliter.

75. Many manufacturers, however, place additional overfill or excess volume in their vials to ensure that patients receive the proper amount from the vial and there is no shortage in the particular injection given to a particular patient. Therefore, the amount of overfill in any particular vial can range from 10% to more than 20% of the volume of the vial.

76. Manufacturers are required to document and report to the FDA the amount and purpose of such overfill and to keep such reporting current. FDA Compliance for Drug Product Formulation Development 2.2.1.

77. The Oncology Drugs at issue are manufactured by "original manufacturers" that have been submitted to and approved through the regulatory process set forth by law and regulation to produce and sell drugs in the United States. There are numerous Oncology Drugs manufactured in single–or multi-dose vials. Examples include Aloxi® which is manufactured by Eisai Inc.; Aranesp® and Neupogen® which is manufactured by Amgen Inc.; Procrit® is manufactured by Ortho Biotech, Inc.; and Taxotere® is manufactured by Sanofi Aventis.

78. The Oncology Drugs would have been manufactured and packaged for distribution and sale by the original manufacturers in accordance with approved FDA standards and would have had individual expiration dates.

79. The single- and multi-use vials of the Oncology Drugs supplied by the original manufacturer to Defendant have a container closure system that was approved by the FDA as part of the application process to the FDA. The original container closure systems meet and are approved as meeting the stability guidance promulgated by the FDA at 21 C.F.R. §§ 166 and 211.137.

80. The single- and multi-use vial containers, in conformity with FDA requirements and having received FDA approval, are shipped from original manufacturers in sealed containers,

marked by lot, and contain the number of units per volume, expiration date, and instructions on storage of the product until it is used for patients as well as the use of the product after use for patients.

81. By way of example, as far back as at least 1993, the package insert for Procrit® stated: "Use only one dose per vial; do not re-enter the vial. Discard unused portions. Contains no Preservative." Since at least July 26, 1999, the package insert for Procit single dose vials has said: "1 ml vial contains no preservative. Use one dose per vial; do not re-enter the vial. Discard unused portions."

82. Since at least October 26, 2005, the Procrit label and packaging were changed to now also state: "If you have been prescribed PROCRIT® vials for single use, your vial will have a capital "S" with a number next to it identifying the concentration of PROCRIT in the vial, printed in a colored dot on the front left side of the label (for example, "S2" identifies a single use vial with 2000 Units/mL). Single use means the vial cannot be used more than once, and any unused portion of the vial should be discarded as directed by your doctor or dialysis center."

83. A November 8, 2007, package insert states: "Unless you have been prescribed Multidose PROCRIT® (1 mL or 2 mL vials with a big "M" on the label, each containing a total of 20,000 Units of PROCRIT®), vials of PROCRIT® are for single use. Single use means the vial cannot be used more than once, and any unused portion of the vial should be discarded as directed by your doctor."

84. And a June 24, 2011 inserts includes the following warnings: "Discard unused portions of Epogen in preservative-free vials. Do not re-enter preservative-free vials...Instruct patients who self-administer Epogen of the: Importance of following the Instructions for Use. Dangers of reusing needles, syringes, or unused portions of single-dose vials....Do not use a

single-dose vial of Epogen more than one time....Single-dose vials of PROCRIT should be used only one time. Throw the vial away after use even if there is medicine left in the vial....Do not reuse the single-dose vials, syringes, or needles."

85. Similar warnings are contained on the package inserts for: Neopogen single-dose vials and pre-filled syringes (since at least April 2, 1998), and Aranesp single-dose vials and pre-filled syringes (since at least July 19, 2002).

86. In addition, since at least December 16, 2004, the package insert for Aranesp has said: "Do not pool unused portions from the vials or prefilled syringes."

87. Overfill itself is not meant to be administered to a patient and is not paid for by the doctor when purchasing the vial from the manufacturer through a distributor.

88. For single-use vials, a physician would order a box of Oncology Drugs containing a number of single-use vials depending on how many patients requiring the Oncology Drugs that the physician expects to have at different times.

89. Once the physician has withdrawn the prescribed amount (up to the labeled amount) from the vial, the residue is supposed to be discarded and may not be billed to any government program.

90. Using Procrit® as an example, one box of single-use vials of Procrit® contains four of the one ml vials; the concentration can vary between 2,000, 3,000, 10,000, and 40,000 units, but the vial is always a one mL vial. Using the 40,000 unit vial, which is the recommended dosage for patients with cancer on chemotherapy, each vial contains overfill of about ten percent above the labeled amount. So instead of having one mL with a 40,000 unit concentration, the vial actually contains 1.1 mL. When the injection is draw, 0.1 mL is left over as residue. The residue is

supposed to be discarded and may not be billed to any government program. The physician can bill only for one mL, and nothing more.

91. For multi-use vials, a physician would order a box of Oncology Drugs containing a number of multi-use vials which, in the case of Procrit®, for example, come in four or six multi-use vials to the box.[1]

92. Again, using Procrit® as an example, which is manufactured in both single- and multi-use vials, the multi-use vials come in two different sizes and concentrations: two ml that has 20K units total (or 10K units per ml) or one ml that has 20K units total (or 20K units per ml). Using the two ml multi-use vial as an example, the vial has a label indicating content of 20K units. However, because of the standard ten percent overfill previously described, in reality the vial may contain 22K or more units. When the injections are drawn, approximately 2K units are left over as residue. The residue is supposed to be discarded and may not be billed to any government program. The physician can bill for 20K units and nothing more.

C. CMS Regulations Forbid Reimbursements for Drug Overfill.

93. CMS sets reimbursement rates for drugs used in the Medicaid and Medicare programs.

94. The Medicare Act reimburses medical providers only for "expenses incurred" for medically necessary items and services. 42 U.S.C. § 1395y(a). Medicare Part B, the program under which dialysis services and the dialysis drugs at issue here are reimbursed, extends coverage only for "expenses incurred" for covered services. 42 U.S.C. § 1395l(a). In 1972, the Medicare Act was amended to cover patients suffering from End Stage Renal Disease ("ESRD") regardless of age.

[1] Aloxi® is only sold by the manufacturer in single-use sterile vials.

Congress provided that Medicare would pay for "the costs incurred" in treating ESRD beneficiaries. 42 U.S.C. §1395rr(b)(2)(B).

95. Medicare pays only the "reasonable costs" of health care services defining reasonable costs as "costs actually incurred" by providers. 42 U.S.C. § 1395x(v)(1)(A)(as to Part A); 1395u(b)(3)(as to Part B). Medicare regulations also require providers to incur costs before they are eligible for reimbursement. 42 C.F.R. § 413.1 (§ 1814(b) of the Act (for Part A) and § 1833(a)(for Part B) provide for payment on the basis of the lesser of a provider's reasonable costs or customary charges) (§ 1861(v) of the Act defines "reasonable costs" [as costs actually incurred.])

96. On July 13, 2010 CMS issued a proposed rule, subject to Notice and Comment, which noted the Agency's intent to make changes to its regulations to clarify its "longstanding policy" under the 'incident to' provisions and ASP reimbursement methodology that providers, may not bill Medicare for free overfill contained in vials of medication. That rule became final on November 29, 2010. CMS reiterated that providers may only be reimbursed if they actually incur costs for a drug, saying "that in order to meet the general requirements for coverage under the 'incident to' provision, services or supplies should represent an expense incurred by the physician or entity billing for the services and supplies . . . . In accordance with this policy, providers may only bill for the amount of drug product actually purchased and the cost of the product must represent an expense to the physician." Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,169, 73,466-67 (November 29, 2010) (to be codified at C.F.R. pts. 405, 409, 410, 411, 413, 414, 415, 424). The statute, and CMS define "the amount of product actually purchased" as the labeled amount of the drug in a container or vial. *Id.*

97. Under CMS regulation 42 CFR § 414.904, "the method of payment for a drug furnished on or after January 1, 2005 is based on the lesser of:

1. the actual charge on the claim for program benefits; or

2. 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

3. For the purposes of this paragraph:

   i. CMS calculates an average sales price payment limit based on the amount of the product included in a vial or other container as reflected on the FDA-approved label.

   ii. Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

   iii. No payment is made for amounts of product in excess of that reflected on the FDA-approved label.

98. CMS regulation 42 CFR § 414.904 is consistent with the CMS policy that services or supplies must represent an expense actually incurred by the physician or medical provider to be reimbursed by Medicare or Medicaid.

99. For instance, the Medicare Reimbursement Policy Manual § 50.3 provides that "[t]he cost of the drug or biological for which reimbursement is sought must represent an expense to the physician." The Medicare Reimbursement Policy Manual § 60.1A further provides that "[t]o be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing for the services or supplies." Medicare Reimbursement Policy Manual, Chapter 15.

100. Because physicians incur no cost for overfill, it is not and never has been reimbursable by Medicare or Medicaid.

101. As stated in the CMS Medicare Claims Processing Manual: "If after administering a dose/quantity of the drug or biological to a Medicare patient, a provider must discard the remainder of the single dose vial, *the program provides payment for the amount of the drug/biological administered and the amount discarded, up to the total amount of the drug/biological as indicated on the vial or package label*." Medicare Claims Processing Manual, Chapter 17, Section 40, revised July 2007 (emphasis added).

102. Since 2005, Medicare has been reimbursing these kinds of injectable drugs under its Part B program, and CMS reimburses based on the ASP, which represents the drug manufacturer's total sales divided by the total number of units sold during the particular quarter. *See* 42 U.S.C. § 1395w-3a(c)(1)(A)-(b). Manufacturers are required to "deduct the price concessions" from the numerator of this mathematical equation, which includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, charge backs, and rebates. *Id.* § 1395w-3a(c)(a); also 42 C.F.R. § 414.804(a)(2)(i). Overfill is not explicitly mentioned in the statute as a type of price concession. Acting in conjunction with the Office of Inspector General ("OIG"), the Secretary of the United States Department of Health and Human Services ("HHS"), which houses CMS, has authority to identify "other price concessions" beyond those already enumerated in the statute, but it has not done so with respect to overfill.

103. In its rulemaking, CMS clearly states that:

> It has been a long standing Medicare policy that to meet the general requirements for coverage under the "incident to" provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies. Such physicians' services and supplies include drugs and biologicals under Section 1861(s)(2)(A) of the Act. In accordance with this policy, provided they only bill for the amount of drug actually purchased and that the cost of the product must represent an expense to the physician.
>
> We further understand that when a provider purchases a vial or container of

> product, provider is purchasing an amount of drug defined by the product packaging or label. Any excess product (that is, overfill) is provided without charge to the provider. In accordance with our current policy as explained above, providers may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursed, and providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.
>
> Because such overfill is currently not included in the calculation of payment limits under the methodology in Section 1847A of the Act and does not represent an incurred cost to the provider, we propose to update our regulations at 42 CFR Part 414 Subpart K to clearly state that the Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We also propose our regulations at Subpart J to clearly state the payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label will not be made under Medicare. . . .

Medicare Programs: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2011, 75 Fed. Reg. 73170, 73466 (Nov. 29, 2010). at 73466-67.

104. CMS promulgated upgraded regulations, which state that "the manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA-approved label," 42 C.F.R. § 414.804(a)(6); that "CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label," id. § 414.904(a)(3)(i); that "additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit," id. § 14.904(a)(3)(ii); and that "no payment is made for amounts of product in excess of that reflected on the FDA-approved label," id. § 414.904(a)(3)(iii).

105. These regulations were specifically highlighted not to be new and substantive changes to previous Medicare policies, but clarifications of existing CMS policies. Specifically, CMS noted that "**the intent of this proposal is merely to clarify** that Medicare ASP payment

limit is based on the amount of drug conspicuously indicated on the FDA label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose." 75 Fed. Reg. at 73467; also id. at 73468 ("[T]he intent of this proposal is to clarify that the ASP payment limit is currently based on the amount of drug indicated on the FDA label, and that no payment will be made for any intentional overfill."), at 73468–69 ("[T]he intent of this proposal is to clarify that the ASP payment limit is based on the amount of drug clearly identified as the amount on the FDA label and packaging. We do not intend to change the ASP calculation methodology to include intentional overfill because of the operational difficulty in accurately identifying the amount of the overfill."), at 73469 ("[O]ur policy clarifies that we will not pay for intentional overfill.")

106. As noted by the regulations above and clarified through the more recent iteration of the CFR, because CMS deemed overfill "not reimbursable," 75 Fed. Reg. at 73466, it can have no independent value attached to it apart from the rest of the dosage in the vial. The only legitimate purpose of overfill is to ensure that providers and self-administering patients are able to draw up the full dosage amount the FDA recommends that manufacturers include it for this purpose. *See* 56 Fed. Reg. at 35978.

107. The industry was thus aware that Medicare prohibited providers from billing for overfill. See Buell, Roberta L., "Drug Wastage: A Payable Service?" Managed Care Oncology(managedcareoncology.com), Q1 2008 ("Medicare provisions prohibit providers from billing overfill." (emphasis in original)); Jim Musslewhite, "The waste conundrum,"Hematology & Oncology News & Issues, Nov. 2009 ("CMS does not permit that overfill be billed due to the fact that it was not purchased.").

II. SPECIFIC ALLEGATIONS OF DEFENDANT'S WRONGDOING.

A. Defendant's Business Model Depends upon Profits from the Billing of Oncology Drugs.

108. U.S. Oncology profits from the sale of Oncology Drugs because it sells the Oncology Drugs to the individual practices and then receives a percentage of the profits from each individual oncology practice in their network.

109. U.S. Oncology employees also provide administrative services to the network offices, including submitting claims to CMS for the individual practices in the U.S. Oncology Network. U.S. Oncology sells its services as: "We take care of the business so you can take care of your patients."

110. As outlined in its 2003 10-K filed with the Securities and Exchange Commission, U.S. Oncology's "core business is providing services to physicians who treat cancer patients. Our services are grouped under four main business lines – oncology pharmaceutical services, cancer center services, cancer research services and practice management services. We provide these services either individually or, in our Physician Practice Management ("PPM") business, bundled together as a comprehensive set of oncology practice management services."

111. "[U.S. Oncology] provides these services through two business models: the physician practice management model, under which we provide all of the above services under a single contract with one fee based on overall performance; and the service line model, under which practices contract with the company to purchase only certain of the above services, each under a separate contract, with a separate fee methodology for each service."

B. Defendant's Scheme to Bill for Overfill.

112. US Oncology kept a record of the average overfill in each different oncology medication vial as different medications contained different amounts of overfill and documents

with these overfill amounts were distributed regularly to members of the US Oncology Network between 2003 and 2014 to encourage and facilitate physicians to administer overfill to patients.

113. U.S. Oncology, as seller of the Oncology Drugs to U.S. Oncology physicians, advocated that its physicians utilize "overfill billing" for the Oncology Drugs administered to patients. The overfill constituted a form of free drug sample or "liquid kickback" in every vial. Yet, unlike traditional free drug samples which are heavily regulated -- *i.e.*, they must be carefully accounted for by drug companies and cannot be the basis for governmental reimbursement -- the free amounts of **overfill** found in every Oncology Drug vial were provided and used by U.S. Oncology physicians without any reporting requirements. The unlawful effect of U.S. Oncology's overfill billing, however, was no different than it would have been had U.S. Oncology billed for free samples: it constituted an illegal kickback.

114. The harvesting of the overfill was either done by the pharmacists or the technicians at each office in the U.S. Oncology Network who were either employed by U.S. Oncology or acted under its direction and the overfill was billed to Government and private payers by staff employed by U.S. Oncology.

115. This practice was widespread amongst US Oncology practices throughout the United States and went on from 2003 through at least October 2014.

116. Defendant's facilities and personnel did not comply with the CGMPs' standards for: personnel engaged in quality control; the design, construction, and maintenance of buildings and facilities; the construction, cleaning, and maintenance of equipment; the storage, inspection, and testing of drug components and containers; the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage, and

distribution; laboratory controls including testing of drug product batches for conformity with final specifications; maintenance of records and reports and conduct of investigations; and procedures for handling of returned and salvaged product.

117. In violation of industry standards, established medical science, and the Oncology Drugs' labeling, Defendant's employees and those under their control punctured original, sterile glass vials more than once and pooled the overfill from the Oncology Drugs, transferring overfill from multiple sources into syringes for delivery to unsuspecting patients. Defendant sought to increase billings for the Oncology Drugs by physicians in order to increase its profits. By encouraging physicians at U.S. Oncology to use overfill from the Oncology Drugs, Defendant created an economic incentive for medical providers to use those drugs, in violation of the law, including the Anti-Kickback Statute and the Federal FCA.

118. Overfill from the Oncology Drugs has value because purchasers are charged for the drug based upon the *labeled* concentration and dosage. Overfill is not reflected on the label and purchasers are *not* charged for the overfill that they receive -- *i.e.*, they do not pay for the extra micrograms of drug that are present in the overfill.

119. Not charging for the overfill is consistent with the intended purpose of overfill, which is to ensure that the labeled dose of the medication can be administered. Overfill itself is not intended to be administered.

120. Defendant's efforts to induce the filing of claims relating to the overfill from the Oncology Drugs were successful. Medical providers within the U.S. Oncology Network submitted claims, examples of which are included in Exhibit 1 hereto, to Medicare and other Government Healthcare Programs to obtain money for overfill (despite the fact that the overfill had not cost the providers anything).

121. The claims submitted by providers within the U.S. Oncology Network to CMS for the Oncology Drugs do not disclose that they are billing for overfill that cost the providers nothing, but that exposes patients to the risk of grievous harm.

122. Defendant, in fact, knew that it was improper for medical providers to file such claims.

123. U.S. Oncology's profits from the sale of the Oncology Drugs to the individual practices and then profits again when the overfill is billed to government and private payers since U.S. Oncology gets a percentage of the profits from the practices in its Network. This gave Defendant a motive to encourage the fraudulent billing of overfill to government and private payers.

C. Defendant's Manipulation of the Average Sales Price ("ASP").

124. CMS determines the reimbursement rate for injectable drugs based on each billing code and using a weighted average sales price calculated with the ASP data submitted by manufacturers.

125. Manufacturers submit ASP data at the eleven-digit NDC level by submitting the number of units of the eleven-digit NDC sold and the ASP for those units.

126. Beginning April 1, 2008, CMS began using a new weighting methodology to determine the payment limit. CMS sums the product of the manufacturer's ASP and the number of units of the eleven-digit NDC sold for each NDC assigned to the billing and payment code, and then divides this total by the sum of the product of the number of units of the eleven-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code. CMS weighs the ASP for an NDC by the number of billing units sold for that NDC.

127. Defendant skewed the ASP process by introducing product into commerce specifically excluded from the calculation of ASP.

128. As such, Defendant was reimbursed at a rate set by CMS through the reported data from the original manufacturer, which yielded a reimbursement rate that was higher per dose than the actual ASP for that drug sold because the Overfill Harvesting by Defendant was never calculated in setting the price, causing damage to the governments.

129. Taking, for example, the calculus used to determine the ASP after April 1, 2008, if the ASP for a specific NDC was $10, and a company sold 50,000 of that NDC, with the total amount of the drug being 2ml and the billing units in the NDCs being 0.4, then the volume weighted ASP for that code would have been the product of $10 and 50,000, divided by the product of 50,000 and 0.4, or $25.

130. However, had the total amount of drug in the NDC accounted for the overfill, and had the overfill been another ten percent, or 0.2ml, giving a total of 2.2ml, or 0.44 billing units in the NDC, then the same calculation would lead to a volume-weighted ASP of $22.73.

131. Defendant is sharing this discount with its healthcare providers by taking a share of its healthcare providers' profits, which includes billing for the free overfill.

132. This allowed Defendant to bill for overfill that was not included in the data reported to CMS to set reimbursement, and, therefore, CMS and government payment programs were paying for more injections than were originally represented to CMS as being in commerce.

D. Defendant's False Certifications to Government Programs.

133. During the relevant time period, Defendant and its agents electronically submitted claims to Medicare Part B for professional services in ANSI ASC X12N 837 Professional format.

Defendant were required to certify, and did certify, by electronically signing each claim submitted to Medicare in 837 Professional format:

> this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law).

134. Additionally, providers like U.S. Oncology are required to annually submit Medicare cost reports (CMS-Form-265-94) which disclose cost data and include an express certification of compliance with all applicable laws as a condition of coverage by Medicare. 42 C.F.R. § 413.20. Other federal and state health care programs also require the annual submission of certified cost reports.

135. U.S. Oncology and its physicians also enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which providers may not seek reimbursement from Federal Health Care Programs, the provider must sign certification that they will abide by all Medicare laws, regulations, and program instructions as well as the Federal Anti-Kickback Statute and the Stark law.

See Form CMS-855A (for institutional providers); Form CMS-855I (for physicians and non-physician practitioners), (effective 2001).

136. The "Certification Statement" that the medical provider must sign also contains the following provisions and requirements inter alia, for "initial and continuous enrollment in the Medicare program," and instructs that by signing the Certification Statement, the provider "agree[s] to adhere to all of the requirements listed therein." (Emphasis added.)

137. Further, it states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." (Emphasis added).

138. By signing the "Certification Statement," the provider certifies, inter alia, to the following:

> 1. I have read the contents of this application, and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare [program] immediately.
> . . .
> 3. I have read and understand the Penalties for Falsifying Information...I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare ...may be punished by criminal, civil or administrative penalties, including but not limited to the denial or revocation of Medicare billing privileges, and/or imposition of fines, civil damages, and/or imprisonment.
> . . .
> 8. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Form 855I

139. The certifications made by the medical provider in the Provider Agreement, which are mandatory for Medicare enrollment, expressly create a continuing duty to comply with the conditions of participation in and payment by the Medicare program. In particular:

(a) Prior to signing the Agreement, the provider is advised of the criminal, civil, and administrative penalties "for deliberately furnishing false information in this application to gain or maintain enrollment in the Medicare program." Section 14 (emphasis added); and

(b) Among those penalties are criminal sanctions for fraud, concealment and any trick, scheme or device or scheme to defraud, any false or fraudulent statement or representation or any false writing or document, violations of the FCA, civil penalties for billing for a medical or other item or services that the provider knows or should know was not provided as claimed. Id. "Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit."

Id.

140. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-Kickback Statue. The provider also makes the following express certification:

In submitting this claim for payment from federal funds, I certify that:

> (1) The information on this form is true, accurate and complete; (2) I have familiarized myself with all applicable laws, regulations and program instructions which are available from the Medicare contractor; (3) I have provided or will provide sufficient information required to allow the government an informed eligibility and payment decision; (4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law, commonly known as Stark law; and (5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision . . . .

E. Elimination of the Oncology Drugs' Pedigree.

141. A particular drug product must maintain a pedigree through its production from the factory to the patient. This is accomplished by issuing a lot number, which allows healthcare providers to trace contamination in any product. By pooling drug product from multiple vials and multiple lots, Defendant destroyed the pedigree of the product delivered to patients and thus there was no longer any way to determine the source of the injections as required by the Prescription Drug Marketing Act, 21 U.S.C. § 503C(1)(A) (the "PDMA"), and FDA Compliance Manual, C.P.G. § 160.900.

142. The absence of a pedigree presents an infection risk to patients already at a higher risk for infections given their immune-compromised state. As previously explained, should the source of an infection be from Defendant's Overfill Harvesting, there would be no way to tell from

which vial the adulterated material actually came from or whether the contamination occurred at Defendant's facilities.

F. Defendant's Awareness of Unsafe Practices.

143. Disturbingly, Defendant, along with the rest of the medical industry, were aware of the danger inherent in these unsafe practices. Indeed, as described in greater detail above, the package inserts for the Oncology Drugs specifically advised Defendant not to engage in the very practices they were encouraging doctors to engage in, specifically re-entering preservative-free vials and pooling the contents of drugs.

144. Additionally, the Centers for Disease Control and Prevention ("CDC") has long been focused on infection control, particularly for high risk patients. Centers for Disease Control and Prevention, *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, available at* https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines.pdf (last visited Jan. 19, 2018). Specifically, the CDC identified a need to focus on safe injection practices following certain "primary breaches in infection control practice that contributed to" four large outbreaks, namely, (i) reinsertion of used needles into multi-dose vials or solution containers; and (ii) use of a single needle/syringe to administer intravenous medication to multiple patients. Id. at 68.

G. Inadequate Compliance Programs, Testing, or Safety Protocols.

145. On information and belief, Defendant had a weak or non-existent compliance program in place. On information and belief, they failed to: (a) conduct a thorough investigation; (b) implement corrective action to terminate and remedy any improper conduct; or (c) disclose the improper conduct to the appropriate agency or US Attorney's Office.

146. On information and belief, Defendant did not have: (a) a lead compliance officer at the senior management level with supervision over the Overfill Harvesting; (b) requirements that middle management periodically certify FCA compliance for their units; (c) an anonymous whistleblower hotline or e-mail system; (d) regular notifications sent to employees informing them how to report a potential FCA or other problem; (e) consistent follow-up on all internal reporting and whistleblowing tips; (f) internal audits of business systems; (g) recurring training regarding the FCA, anti-fraud and anti-kickback policies, and employees' obligation to report potential wrongdoing; (h) widespread availability of an updated compliance guidebook tailored to the company's industry and policies; (i) consistent messaging from management and supervisors emphasizing the importance of compliance with the FCA or FDCA

147. By pooling Oncology Drug liquid overfill from the single - and multi-use vials and administering the pooled overfill to oncology patients, Defendant were creating and selling adulterated and compounded drugs, which may not be sold in commerce and which are not reimbursable by any governmental or private insurance company. This would apply to the all Oncology Drugs administered by Defendant under the Overfill Harvesting.

148. Had the federal government, District of Columbia, state, or local governments been aware of the conduct alleged in this Complaint, they would not have paid the claims that were submitted as a result of Defendant's misconduct.

CLAIMS FOR RELIEF

COUNT 1
Federal False Claims Act: Presentation of False Claims
(31 U.S.C. § 3729(a)(1))

149. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

150. By virtue of the acts alleged herein, Defendant, through the acts of their officers, agents, employees, and sales representatives and for the purpose of defrauding the Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Medicare, Medicaid, and other Government health programs to officers, employees, or agents of the United States Government, in violation of 31 U.S.C. § 3729(a)(1).

151. As a result, federal monies were lost through payments made in connection with the claims and other costs and losses were sustained by the Government, and Defendant are liable for treble damages plus the maximum civil penalty of $10,000 for each and every false and fraudulent claim made and caused to be made by Defendant before 2010, and $11,000 for each and every false and fraudulent claim made and caused by be made by Defendant after 2010, and arising from their conduct as described herein.

COUNT 2
Federal False Claims Act: False Statements
(31 U.S.C. § 3729(a)(2))

152. Relator re-alleges and incorporates the preceding paragraphs of this Complaint as is fully set forth herein.

153. In performing the acts described above, Defendant, through the acts of their officers, agents, employees and sales representatives, knowingly made, used, or caused to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the Government in violation of 31 U.S.C § 3729(a)(2).

154. The United States, unaware of the foregoing circumstances and conduct of Defendant, made full payments, and Defendant are liable for treble damages plus the maximum civil penalty of $10,000 for each and every false and fraudulent claim paid or approved before

2010, and $11,000 for each and every false and fraudulent claim paid or approved after 2010, arising from Defendant's conduct as described herein.

COUNT 3
Unjust Enrichment

155. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

156. The Defendant colluded amongst themselves to convey benefits on Defendant to the detriment of Plaintiffs.

157. Defendant caused themselves to be enriched and conveyed benefits on themselves at the expense of the United States of America, District of Columbia, states, and cities under circumstances where it would be inequitable for Defendant to retain the benefits conveyed.

158. The benefits conveyed to Defendant were conveyed independent from, and outside the scope of, any agreement between Plaintiffs and Defendant.

159. In equity and good conscience, it would be unfair for Defendant to retain any such benefits.

160. Each Defendant should be required to disgorge any such benefit in amounts to be determined at trial to Plaintiffs.

COUNT 4
California False Claims Act
(Cal. Gov't Code § 12651(a)(1))

161. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

162. This is a claim for penalties and treble damages for violation of the California False Claims Act.

163. By virtue of the acts described above, Defendant, for the purpose of defrauding the California State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other California State-funded programs to officers or employees of the state within the meaning of Cal. Gov't Code § 12651(a)(1).

164. By virtue of the acts described above, Defendant, for the purpose of defrauding the California State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other California State-funded programs within the meaning of Cal. Gov't Code § 12651(a)(2).

165. The California State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

166. As a result, California State monies were lost through payments made because of the claims, and other costs and losses were sustained by the California State Government.

167. Therefore, the California State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

168. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 5
Colorado Medicaid False Claims Act
(C.R.S.A. § 25.5-4-300.4 *et seq.*)

169. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

170. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

171. By virtue of the acts described above, Defendant, for the purpose of defrauding the Colorado State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Colorado State-funded programs within the meaning of C.R.S.A § 25.5-4-304.

172. The Colorado State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

173. As a result, Colorado State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Colorado State Government.

174. Therefore, the Colorado State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

175. Additionally, the Colorado State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendant's conduct as described herein as well as costs as permitted under the statute.

COUNT 6
Connecticut False Claims Act
(C.G.S.A. § 17b-301 *et seq.*)

176. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

177. This is a claim for penalties and treble damages under the Connecticut False Claims Act.

178. By virtue of the acts described above, Defendant, for the purpose of defrauding the Connecticut State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Connecticut State-funded programs within the meaning of C.G.S.A § 17b-301(a) and (b).

179. The Connecticut State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

180. As a result, Connecticut State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Connecticut State Government.

181. Therefore, the Connecticut State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

182. Additionally, the Connecticut State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendant's conduct as described herein as well as costs as permitted under the statute.

COUNT 7
Delaware False Claims and Reporting Act
(6 Del. C. § 1201 *et seq.*)

183. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

184. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

185. By virtue of the acts described above, Defendant, for the purpose of defrauding the Delaware State Government, knowingly presented and/or caused to be presented, directly or indirectly, false or fraudulent claims for payment or approval under Medicaid and other Delaware State-funded programs to officers or employees of the state within the meaning of 6 Del. C. § 1201(a)(1).

186. By virtue of the acts described above, Defendant, for the purpose of defrauding the Delaware State Government, knowingly made, used, and/or caused to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Delaware State-funded programs within the meaning of 6 Del. C. § 1201(a)(2).

187. The Delaware State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

188. As a result, Delaware State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Delaware State Government.

189. Therefore, the Delaware State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted under the statute.

190. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 8
District of Columbia Procurement Reform Amendment Act
(D.C. Code § 2-308 *et seq.*)

191. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

192. This is a claim for penalties and treble damages under the District of Columbia Procurement Reform Amendment Act.

193. By virtue of the acts described above, Defendant, for the purpose of defrauding the District of Columbia Government, knowingly presented and/or caused to be presented, false claims for payment or approval under Medicaid and other District of Columbia-funded programs to officers or employees of the District within the meaning of D.C. Code § 2-308.14(a)(1).

194. By virtue of the acts described above, Defendant, for the purpose of defrauding the District of Columbia Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other District of Columbia-funded programs within the meaning of D.C. Code § 2- 308.14(a)(2).

195. The District of Columbia Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

196. As a result, District of Columbia monies were lost through payments made because of the claims, and other costs and losses were sustained by the District of Columbia Government.

197. Therefore, the District of Columbia Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

198. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 9
Florida False Claims Act
(Fla. Stat. § 68.082 *et seq.*)

199. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

200. This is a claim for penalties and treble damages under the Florida False Claims Act.

201. By virtue of the acts described above, Defendant, for the purpose of defrauding the Florida State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Florida State-funded programs to officers or employees of the state within the meaning of Fla. Stat. § 68.082(2)(a).

202. By virtue of the acts described above, Defendant, for the purpose of defrauding the Florida State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Florida State-funded programs within the meaning of Fla. Stat. § 68.082(2)(b).

203. The Florida State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

204. As a result, Florida State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Florida State Government.

205. Therefore, the Florida State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

206. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 10
Georgia State False Medicaid Claims Act
(Ga. Code Ann. § 49-4-168 *et seq.*)

207. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

208. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

209. By virtue of the acts described above, Defendant, for the purpose of defrauding the Georgia State Government, knowingly presented and/or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval within the meaning of Ga. Code Ann. § 49-4-168.1(a)(1).

210. By virtue of the acts described above, Defendant, for the purpose of defrauding the Georgia State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program within the meaning of Ga. Code Ann. § 49-4-168.1(a)(2).

211. The Georgia State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

212. As a result, Georgia State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Georgia State Government.

213. Therefore, the Georgia State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

214. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented or caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 11
Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21 *et seq.*)

215. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

216. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

217. By virtue of the acts described above, Defendant, for the purpose of defrauding the Hawaii State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Hawaii State-funded programs to officers or employees of the state within the meaning of Haw. Rev. Stat. § 661-21(a)(1).

218. By virtue of the acts described above, Defendant, for the purpose of defrauding the Hawaii State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Hawaii State-funded programs within the meaning of Haw. Rev. Stat. § 661-21)(a)(2).

219. The Hawaii State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

220. As a result, Hawaii State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Hawaii State Government.

221. Therefore, the Hawaii State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

222. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 12
Illinois Whistleblower Reward and Protection Act
(740 Ill. Comp. Stat. § 175/3(a))

223. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

224. This is a claim for penalties and treble damages under the Illinois Whistleblower Reward and Protection Act.

225. By virtue of the acts described above, Defendant, for the purpose of defrauding the Illinois State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Illinois State-funded programs to officers or employees of the state within the meaning of 740 Ill. Comp. Stat. § 175/3(a)(1).

226. By virtue of the acts described above, Defendant, for the purpose of defrauding the Illinois State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Illinois State-funded programs within the meaning of 740 Ill. Comp. Stat. § 175/3(a)(2).

227. The Illinois State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

228. As a result, Illinois State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Illinois State Government.

229. Therefore, the Illinois State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

230. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 13
Indiana False Claims and Whistleblower Protection Act
(Ind. Code § 5-11-5.5-2 *et seq.*)

231. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

232. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

233. By virtue of the acts described above, Defendant, for the purpose of defrauding the Indiana State Government, knowingly or intentionally presented and/or caused or induced another to present false claims under Medicaid and other Indiana State-funded programs to the state for payment or approval within the meaning of Ind. Code § 5-11-5.5-2(b)(1) and (8).

234. By virtue of the acts described above, Defendant, for the purpose of defrauding the Indiana State Government, knowingly or intentionally made, used, and/or caused or induced another to make or use, false records or statements to obtain payment or approval of a false claim under Medicaid and other Indiana State-funded programs within the meaning of Ind. Code § 5-11-5.5-2(b)(2) and (8).

235. The Indiana State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

236. As a result, Indiana State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Indiana State Government.

237. Therefore, the Indiana State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

238. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from Defendant's conduct as describe herein.

COUNT 14
Iowa False Claims Act
(I.C.A. § 685.2 *et seq.*)

239. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

240. This is a claim for penalties and treble damages under the Iowa False Claims Act.

241. By virtue of the acts described above, Defendant, for the purpose of defrauding the Iowa State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Iowa State-funded programs within the meaning of I.C.A. § 685.2et seq.

242. The Iowa State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

243. As a result, Iowa State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Iowa State Government.

244. Therefore, the Iowa State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

245. Additionally, the Iowa State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendant's conduct as described herein as well as costs as permitted under the statute.

COUNT 15
Louisiana Medical Assistance Programs Integrity Law
(La. Rev. Stat. § 46:438.3(A) and (B))

246. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

247. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

248. By virtue of the acts described above, Defendant, for the purpose of defrauding the Louisiana State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Louisiana State-funded programs within the meaning of La. Rev. Stat. § 46:438.3(A).

249. By virtue of the acts described above, Defendant, for the purpose of defrauding the Louisiana State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of La. Rev. Stat. § 46:483.3(B).

250. The Louisiana State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

251. As a result, Louisiana State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Louisiana State Government.

252. Therefore, the Louisiana State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

253. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. § 46:438.6(B)(2).

COUNT 16
Maryland False Claims Act
(Md. Code Health General § 2-601 *et seq.*)

254. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

255. This is a claim for a fine and damages under the Maryland False Claims Act.

256. By virtue of the acts described above, Defendant, for the purpose of defrauding the Maryland State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of Md. Code Health General § 2-601-602).

257. The Maryland State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

258. As a result, Maryland State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Maryland State Government.

259. Therefore, the Maryland State Government has been damaged in an amount to be proved at trial.

260. Additionally, the Maryland State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. Md. Code Health General §2-602).

COUNT 17
Massachusetts False Claims Act
(Mass. Gen. L. Ch. 12, § 5B(2))

261. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

262. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

263. By virtue of the acts described above, Defendant, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth within the meaning of Mass. Gen. L. Ch. 12, § 5B(2).

264. The Massachusetts Commonwealth Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

265. As a result, Massachusetts Commonwealth monies were lost through payments made because of the claims, and other costs and losses were sustained by the Massachusetts Commonwealth Government.

266. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

267. Additionally, the Massachusetts Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendant's conduct as described herein.

COUNT 18
Michigan Medicaid False Claims Act
(Mich. Comp. Laws § 400.601 *et seq.*)

268. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

269. This is a claim for damages and a civil penalty under the Michigan Medicaid False Claims Act.

270. By virtue of the acts described above, Defendant, for the purpose of defrauding the Michigan State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Michigan a claim under the Social Welfare Act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the State, knowing the claim to be false within the meaning of Mich. Comp. Law § 400.601 et seq.

271. The Michigan State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

272. As a result, Michigan State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Michigan State Government.

273. Therefore, the Michigan State Government has been damaged in an amount to be proved at trial.

274. Additionally, the Michigan State Government is entitled to a civil penalty equal to the full amount of the benefit received by Defendant plus triple the amount of damages suffered by the state as a result of the conduct by Defendant as described herein.

COUNT 19
Minnesota False Claims Act
(Minn. Stat. § 15C.01 *et seq.*)

275. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

276. This is a claim for penalties and treble damages under the Minnesota False Claims Act.

277. By virtue of the acts described above, Defendant, for the purpose of defrauding the Minnesota Government, knowingly made, used, and/or caused to be made or used, false records

or statements to obtain payment or approval of claims by the Minnesota Government within the meaning of Minn. Stat § 15C.01.

278. The Minnesota Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

279. As a result, Minnesota monies were lost through payments made because of the claims, and other costs and losses were sustained by the Minnesota Government.

280. Therefore, the Minnesota Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

281. Additionally, the Minnesota Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendant's conduct as described herein as well.

COUNT 20
Montana False Claims Act
(M.C.A. § 17-8-401 *et seq.*)

282. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

283. This is a claim for damages and a civil penalty under the Montana Medicaid False Claims Act.

284. By virtue of the acts described above, Defendant, for the purpose of defrauding the Montana State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Montana a claim knowing the claim to be false within the meaning of M.C.A. § 17-8-402.

285. The Montana State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

286. As a result, Montana State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Montana State Government.

287. Therefore, the Montana State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

288. Additionally, the Montana State Government is entitled to a civil penalty equal to the full amount of the benefit received by Defendant plus triple the amount of damages suffered by the state as a result of the conduct by Defendant as described herein.

COUNT 21
Nevada False Claims Act
(Nev. Rev. Stat. § 357.040(1)(a))

289. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

290. This is a claim for penalties and treble damages under the Nevada False Claims Act, titled "Submission of False Claims to State or Local Government."

291. By virtue of the acts described above, Defendant, for the purpose of defrauding the Nevada State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Nevada State-funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(a).

292. By virtue of the acts described above, Defendant, for the purpose of defrauding the Nevada State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Nevada State-funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(b).

293. The Nevada State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

294. As a result, Nevada State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Nevada State Government.

295. Therefore, the Nevada State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

296. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 22
New Hampshire False Claims Act
(N.H. Rev. Stat. Ann. § 167:61-b(I)(a)-(b))

297. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

298. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

299. By virtue of the acts described above, Defendant, for the purpose of defrauding the New Hampshire State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New Hampshire State-funded programs to officers or employees of the state within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(a).

300. By virtue of the acts described above, Defendant, for the purpose of defrauding the New Hampshire State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Hampshire State-funded programs within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(b).

301. The New Hampshire State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

302. As a result, New Hampshire State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Hampshire State Government.

303. Therefore, the New Hampshire State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

304. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 23
New Jersey False Claims Act
(N.J.S.A. § 2A:32C-1 *et seq.*)

305. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

306. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

307. By virtue of the acts described above, Defendant, for the purpose of defrauding the New Jersey State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Jersey State-funded programs to the State within the meaning of N.J.S.A. § 2A:32C-2.

308. The New Jersey State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

309. As a result, New Jersey State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Jersey State Government.

310. Therefore, the New Jersey State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

311. Additionally, the New Jersey State Government is entitled to the maximum penalty under N.J.S.A. § 2A:32C-3 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 24
New Mexico Medicaid False Claims Act
(N.M. Stat. Ann. § 27-14-4 *et seq.*)

312. The Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

313. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

314. By virtue of the acts described above, Defendant, for the purpose of defrauding the New Mexico State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State-funded programs to the State within the meaning of N.M. Stat. Ann. § 27-14-4(A).

315. By virtue of the acts described above, Defendant, for the purpose of defrauding the New Mexico State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Mexico State-funded programs within the meaning of N.M. Stat. Ann. § 27-14-4(C).

316. The New Mexico State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

317. As a result, New Mexico State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Mexico State Government.

318. Therefore, the New Mexico State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

319. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 25
New York False Claims Act
(N.Y. State Fin. Law § 189(1)(a)-(b))

320. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

321. This is a claim for penalties and treble damages under the New York False Claims Act.

322. By virtue of the acts described above, Defendant, for the purpose of defrauding the New York State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York State-funded programs to officers or employees or agents of the state within the meaning of N.Y. State Fin. Law § 189(1)(a).

323. By virtue of the acts described above, Defendant, for the purpose of defrauding the New York State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York State-funded programs within the meaning of N.Y. State Fin. Law § 189(1)(b).

324. The New York State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

325. As a result, New York State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New York State Government.

326. Therefore, the New York State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

327. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 26
North Carolina False Claims Act
(N.C.G.S.A. § 1-605 *et seq.*)

328. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

329. This is a claim for penalties and treble damages under the North Carolina False Claims Act.

330. By virtue of the acts described above, Defendant, for the purpose of defrauding the North Carolina State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other North Carolina State-funded programs to officers or employees of the state within the meaning of N.C.G.S.A. § 1-606.

331. The North Carolina State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

332. As a result, North Carolina State monies were lost through payments made because of the claims, and other costs and losses were sustained by the North Carolina State Government.

333. Therefore, the North Carolina State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

334. Additionally, the North Carolina State Government is entitled to the maximum penalty of $11,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 27
Oklahoma Medicaid Program Integrity Act
(56 Okl. St. Ann. § 1001 *et seq.*)

335. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

336. This is a claim for penalties and treble damages under the Oklahoma False Claims Act.

337. By virtue of the acts described above, Defendant, for the purpose of defrauding the Oklahoma State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Oklahoma State-funded programs to officers or employees of the state within the meaning of 56 Okl. St. Ann. § 1005.

338. The Oklahoma State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

339. As a result, Oklahoma State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Oklahoma State Government.

340. Therefore, the Oklahoma State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

341. Additionally, the Oklahoma State Government is entitled under 56 Okl. St. Ann. § 1006 to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 28
Rhode Island State False Claims Act
(Gen. Laws 1956, § 9-1.1-1)

342. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

343. This is a claim for penalties and treble damages under the Rhode Island State False Claims Act.

344. By virtue of the acts described above, Defendant, for the purpose of defrauding the Rhode Island State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Rhode Island State-funded programs to officers or employees of the state within the meaning of Gen. Laws 1956, § 9-1.1-3.

345. The Rhode Island State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

346. As a result, Rhode Island State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Rhode Island State Government.

347. Therefore, the Rhode Island State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

348. Additionally, the Rhode Island State Government is entitled under Gen. Laws 1956, § 9-1.1-3 to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 29
Tennessee False Claims Act
(Tenn. Code Ann. § 4-18-103(a)(1)-(2))

349. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

350. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

351. By virtue of the acts described above, Defendant, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Tennessee State-funded programs to officers or employees of the state within the meaning of Tenn. Code Ann. § 4-18-103(a)(1).

352. By virtue of the acts described above, Defendant, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Tennessee State-funded programs within the meaning of Tenn. Code Ann. § 4-18-03(a)(2).

353. The Tennessee State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

354. As a result, Tennessee State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Tennessee State Government.

355. Therefore, the Tennessee State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

356. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 30
Tennessee Medicaid False Claims Act
(Tenn. Code Ann. § 71-5-182(a)(1)(A)-(B))

357. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

358. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

359. By virtue of the acts described above, Defendant, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented to the state claims for payment under the Medicaid program knowing such claims were false or fraudulent within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(A).

360. By virtue of the acts described above, Defendant, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the state knowing such record or statement were false within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(B).

361. The Tennessee State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

362. As a result, Tennessee State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Tennessee State Government.

363. Therefore, the Tennessee State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

364. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from Defendant's conduct as described herein.

COUNT 31
Texas Medicaid Fraud Prevention Law
(Tex. Hum. Res. Code § 36.002 *et seq.*)

365. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

366. This is a claim for restitution, interest, penalties and double damages under the Texas Medicaid Fraud Prevention Law.

367. By virtue of the acts described above, Defendant, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, and/or caused to be made, false statements or representations of material facts on applications for contracts, benefits, or payments under the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(1)(A).

368. By virtue of the acts described above, Defendant, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, caused to be made, induced, and/or sought to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(4)(B).

369. The Texas State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

370. As a result, Texas State monies were lost through payments made because of the false statements or representations, and other costs and losses were sustained by the Texas State Government.

371. Therefore, the Texas State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

372. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by Defendant under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

COUNT 32
Vermont False Claims Act
(32 V.S.A. § 632)

373. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

374. This is a claim for penalties and treble damages under the Vermont False Claims Act.

375. By virtue of the acts described above, Defendant, for the purpose of defrauding the Vermont State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Vermont State-funded programs to officers or employees of the State within the meaning of 32 V.S.A. § 632.

376. By virtue of the acts described above, Defendant, for the purpose of defrauding the Vermont State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State under Medicaid and other Vermont-State-funded programs within the meaning of 32 V.S.A. § 632.

377. The Vermont State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

378. As a result, Vermont State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Vermont State Government.

379. Therefore, the Vermont State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

380. Additionally, the Vermont State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 33
Virginia Fraud Against Taxpayers Act
(Va. Code Ann. § 8.01-216.3(A)(1)-(2))

381. Relator re-alleges and incorporates all of the preceding paragraphs of the Complaint as if fully set forth herein.

382. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

383. By virtue of the acts described above, Defendant, for the purpose of defrauding the Virginia Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Virginia Commonwealth-funded programs to officers or employees of the Commonwealth within the meaning of Va. Code Ann. § 8.01-216.3(A)(1).

384. By virtue of the acts described above, Defendant, for the purpose of defrauding the Virginia Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth under Medicaid and other Virginia Commonwealth-funded programs within the meaning of Va. Code Ann. § 8.01-216.3(A)(2).

385. The Virginia Commonwealth Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

386. As a result, Virginia Commonwealth monies were lost through payments made because of the claims, and other costs and losses were sustained by the Virginia Commonwealth Government.

387. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

388. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 34
Washington False Claims Act
(RCW § 48.80.030)

389. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

390. This is a claim for penalties and treble damages under the Washington False Claims Act.

391. By virtue of the acts described above, Defendant, for the purpose of defrauding the Washington State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Vermont State-funded programs to officers or employees of the State within the meaning of RCW § 48.80.030.

392. By virtue of the acts described above, Defendant, for the purpose of defrauding the Washington State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State under Medicaid and other Washington-State-funded programs within the meaning of RCW § 48.80.030.

393. The Washington State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

394. As a result, Washington State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Washington State Government.

395. Therefore, the Washington State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

396. Additionally, the Washington State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 35
Wisconsin Medical Assistance False Claims Act
(W.S.A. §§ 49.485, 49.49)

397. Relator re-alleges and incorporates all the preceding paragraphs of the Complaint as if fully set forth herein.

398. This is a claim for penalties and treble damages under the Wisconsin Medical Assistance False Claims Act.

399. By virtue of the acts described above, Defendant, for the purpose of defrauding the Wisconsin Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State under Medicaid and other Wisconsin State-funded programs within the meaning of W.S.A. §§ 49.485, 49.49.

400. The Wisconsin State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

401. As a result, Wisconsin State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Wisconsin State Government.

402. Therefore, the Wisconsin State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

403. Additionally, the Wisconsin State Government is entitled under to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from Defendant's conduct as described herein.

COUNT 36
Chicago False Claims Act
(Chicago Mun. Code Ch. 1-22-020(1)-(2))

404. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

405. This is a claim for penalties and treble damages under the Chicago False Claims Act.

406. By virtue of the acts described above, Defendant, for the purpose of defrauding the Chicago City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Chicago City-funded programs to officers or employees of the City within the meaning of Chicago Mun. Code Ch. 1-22-020(1).

407. By virtue of the acts described above, Defendant, for the purpose of defrauding the Chicago City Government, knowingly made, used, and/or caused to be made or used, false records or statement to get false claims paid or approved under Medicaid and other Chicago City-funded programs within the meaning of Chicago Mun. Code Ch. 1-22-020(2).

408. The Chicago City Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

409. As a result, Chicago City monies were lost through payments made because of the claims, and other costs and losses were sustained by the Chicago City Government.

410. Therefore, the Chicago City Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

411. Additionally, the Chicago City Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 37
New York City False Claims Act
(NYC Admin. Code § 7-803(a)(1))

412. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

413. This is a claim for penalties and treble damages under the New York City False Claims Act.

414. By virtue of the acts described above, Defendant, for the purpose of defrauding the New York City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York City-funded programs to officers or employees of the City within the meaning of NYC Admin. Code § 7-803(a)(1).

415. By virtue of the acts described above, Defendant, for the purpose of defrauding the New York City Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York City-funded programs within the meaning of NYC Admin. Code § 7-803(a)(2).

416. The New York City Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendant's practices.

417. As a result, New York City monies were lost through payments made because of the claims, and other costs and losses were sustained by the New York City Government.

418. Therefore, the New York City Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

419. Additionally, the New York City Government is entitled to the maximum penalty of $15,000 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 37
California Insurance Frauds Prevention Act
(Cal. Ins.Code § 1871.7)

420. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

421. This is a claim for penalties and treble damages under the California Insurance Frauds Prevention Act.

422. By virtue of the acts described above, Defendant, for the purpose of defrauding the private insurers and the insured, knowingly presented and/or caused to be presented false claims for payment or approval of claims under the meaning of Cal. Ins.Code § 1871.7.

423. By virtue of the acts described above, Defendant, for the purpose of defrauding private insurers in the state of California, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved.

424. Private insurers, unaware of the falsity, paid claims that they would not have paid had it known of Defendant's practices.

425. As a result, monies were lost by private insurers through payments made because of the claims, and other costs and losses were sustained.

426. Therefore, private insurers in the state of California have been damaged in an amount to be proved at trial and California is entitled to treble damages as permitted by statute.

427. Additionally, the state of California is entitled to the maximum penalty allowed under Section 1871 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

COUNT 37
Illinois Insurance Claims Fraud Prevention Act
(740 ILCS 92/5)

428. Relator re-alleges and incorporates the preceding paragraphs of the Complaint as if fully set forth herein.

429. This is a claim for penalties and treble damages under the Illinois Insurance Claims Fraud Prevention Act.

430. By virtue of the acts described above, Defendant, for the purpose of defrauding the private insurers and the insured, knowingly presented and/or caused to be presented false claims for payment or approval of claims under the meaning of 740 ILCS 92/5.

431. By virtue of the acts described above, Defendant, for the purpose of defrauding private insurers in the state of Illinois, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved.

432. Private insurers, unaware of the falsity, paid claims that they would not have paid had it known of Defendant's practices.

433. As a result, monies were lost by private insurers through payments made because of the claims, and other costs and losses were sustained.

434. Therefore, private insurers in the state of Illinois have been damaged in an amount to be proved at trial and the state of Illinois is entitled to treble damages as permitted by statute.

435. Additionally, the state of Illinois is entitled to the maximum penalty allowed under Section 740 ILCS 92/5 for each and every false claim presented and caused to be presented by Defendant and arising from their conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for the following relief:

A. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the United States, plus a civil penalty of up to $10,000 for each violation of 31 U.S.C. § 3729 proved at trial;

B. Judgment in amount of proven damages at trial for payment in mistake of fact and unjust enrichment;

C. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of California, plus a civil penalty of $10,000 for each violation of Cal. Gov't Code § 12651 proved at trial;

D. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Colorado, plus a penalty of $10,000 for each violation of the Colorado False Claims Act, C.R.S.A § 25.5-4-304, as well as costs as permitted under the statute;

E. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Connecticut, plus a penalty of $10,000 for each violation of the Connecticut State funded programs within the meaning of C.G.S.A § 17b-301(a) and 301(b), as well as costs as permitted under the statute;

F. Judgment in an amount equal to treble damages to be proved at trial against Defendant and in favor of the State of Delaware, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201 proved at trial;

G. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the District of Columbia, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14 proved at trial;

H. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Florida, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082 proved at trial;

I. Judgment in an amount equal to threefold the damages to be proved at trial against Defendant and in favor of the State of Georgia, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. § 49-4-168.1 proved at trial;

J. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Hawaii, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21 proved at trial.

K. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Illinois, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3 proved at trial;

L. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Indiana, plus a civil penalty of at least $5,000 for each violation of Ind. Code § 5-11-5.5-2(b) proved at trial;

M. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Iowa, plus a civil penalty of at least $10,000 for each violation of the Iowa False Claims Act proved at trial as well as costs as permitted by statute;

N. Judgment in an amount equal to the damages to be proved at trial against Defendant and in favor of the State of Louisiana, plus a civil fine in the amount of three times the amount of actual damages sustained for each violation of La. Rev. Stat. 46:438.3 proved at trial;

O. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Maryland;

P. Judgment in an amount equal to threefold the damages to be proved at trial against Defendant and in favor of the Commonwealth of Massachusetts, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12, § 5B proved at trial;

Q. Judgment in an amount equal to the damages to be proved at trial against Defendant and in favor of the State of Michigan, plus a civil penalty equal to the full amount of the benefit received by the Defendant plus triple the amount of damages suffered by the state for each violation of Mich. Comp. Laws § 400.610a proved at trial;

R. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Minnesota, plus a civil penalty of $10,000 for each violation of Minn. Stat § 15C.01 proved at trial;

S. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Montana;

T. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Nevada, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040 proved at trial;

U. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of New Hampshire, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I) proved at trial;

V. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of New Jersey, plus a civil penalty of $10,000 for each violation of N.J.S.A. § 2A:32C-2 proved at trial;

W. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of New Mexico, plus a civil penalty for each violation of N.M. Stat. Ann. § 27-14-4 proved at trial;

X. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of New York, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. Law § 189 proved at trial;

Y. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of North Carolina, plus a civil penalty of $11,000 for each violation of N.C.G.S.A. § 1-606 proved at trial.

Z. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Oklahoma, plus a civil penalty of $10,000 for each violation proved at trial pursuant to 56 Okl. St. Ann. §1006;

AA. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Oklahoma, plus a civil penalty of $10,000 for each violation proved at trial pursuant Gen. Laws 1956, § 9-1.1-3;

BB. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § Tenn. Code Ann. § 4-18-103 proved at trial;

CC. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182 proved at trial;

DD. Judgment in an amount equal to restitution, interest, and two times the damages to be proved at trial against Defendant and in favor of the State of Texas, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002 proved at trial;

EE. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Vermont, plus a civil penalty of $11,000 for each violation of 32 V.S.A. § 632 proved at trial;

FF. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the Commonwealth of Virginia, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3 proved at trial;

GG. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Washington, plus a civil penalty of $11,000 for each violation of Washington-State-funded programs within the meaning of RCW § 48.80.030 proved at trial.

HH. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the State of Wisconsin plus a civil penalty of $10,000 for each violation proved at trial pursuant W.S.A. §§ 49.485; 49.49;

II. Judgment in an amount equal to treble the damages to be proved at trial against Defendant and in favor of the City of Chicago, plus a civil penalty of $10,000 for each violation of Chicago Mun. Code ch. 1-22-020 proved at trial;

JJ. Judgment in an amount equal to threefold the damages to be proved at trial against Defendant and in favor of the City of New York, plus a civil penalty of $15,000 for each violation of NYC Admin. Code § 7-803 proved at trial;

KK. Judgment in an amount equal to treble damages to be proved at trial against Defendant and in favor of the state of California, plus a civil penalty of the maximum allowed under Section 1871.7 of the California Insurance Code.

LL. Judgment in an amount equal to treble damages to be proved at trial against Defendants and in favor of the state of Illinois, plus a civil penalty of the maximum allowed under 740 ILCS 92/5 of the Illinois Insurance Code.

MM. An award to Relator of the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and equivalent provisions in the state statutes set forth above, including the costs and expenses of this action and reasonable attorneys' fees;

NN. All such other, further and different relief, whether preliminary or permanent, legal, general or equitable, as the Court deems just and proper.

JURY DEMAND

Relator hereby demands a trial by Jury in this matter.

Dated: Sept 4, 2019

Respectfully submitted,

BOIES SCHILLER FLEXNER, LLP

By: _____

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